 MAY - 4 2006

Exhibit #1 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K053234

Submitter:

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Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
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- **Contact Person:**

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Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

Oct. 25, 2005

Name of the device:

- **Trade/Proprietary Name:** PM-9000 Express Patient Monitor
- **Common Name:** Patient Monitor
- **Classification**

21 CFR 870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	Class II
21 CFR 870.1130	Non-Invasive blood pressure measurement System	Class II
21 CFR 870.1110	Blood pressure computer	Class II
21 CFR 880.2910	Clinical Electronic Thermometers – Temperature Monitor with Probe	Class II
21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 870.2710	Ear Oximeter, Pulse	Class II
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	Class II

21 CFR 868.1500	Enflurane gas analyzer	Class II
21 CFR 868.1620	Halothane gas analyzer	Class II
21 CFR 868.1700	Nitrous Oxide gas analyzer	Class II
21 CFR 868.1720	Oxygen gas analyzer	Class II

Legally Marketed Predicate Device:

K043348 PM-8000 Patient Monitor (by Mindray Co., Ltd.)

K030038 IntelliVue Models MP60, MP70 and MP90 Patient Monitors with portal Technology and M3185 opt. C41 Wireless Bedside(by Philips Co., Ltd.)

Description:

The PM-9000 Express Patient Monitor is a battery or line-powered patient monitor. The Patient Monitor acquires the physiological signals such as ECG, respiration (RESP), non-invasive blood pressure (NIBP), saturation of pulse oxygen (SpO_2), temperature (TEMP), invasive pressure (IBP), carbon dioxide(CO_2) and anaesthetic gases(AG). These physiological signals are converted into digital data and processed. The PM-9000 Express Patient Monitor examines the data for alarm conditions and presents them on the color TFT display. The Patient Monitor also provides advantageous operating control for the user.

The optional built-in recorder, the optional CF memory card provides hard copies of all digital data and waveforms as well as Tabular and Graphic Trend Information, and storage the previous monitoring data information when power off accidentally.

Statement of intended Use:

The PM-9000 Express Patient Monitor is a vital signs monitor used on human patients. The target populations are adult, pediatric and neonatal patients. The PM-9000 Express Patient Monitor has many features and functions, yet is easy to use through an integrated keypad, knob and an intuitive menu system.

The patient parameters that can be monitored by PM-9000 Express Patient Monitor are: ECG(3-lead or 5-lead selectable), Heart Rate(HR), Pulse Rate(PR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Saturation of Pulse Oxygen(SpO_2), Temperature (TEMP), Invasive Blood Pressure(IBP), Carbon Dioxide (CO_2), and Anaesthetic Gases(AG). Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The PM-9000 Express Patient Monitor is intended for use in health care facility setting. It is intended for use by qualified medical personnel trained in the use of the equipment.

The PM-9000 Express Patient Monitor is not recommended for use in a patient's home or residence, or when it has not been ordered by a physician.

Comparison of Technological Characteristics:

The PM-9000 Express Patient Monitor is substantially equivalent to systems currently marketed predicate devices. The design, components, storage technology and energy source of the PM-9000 Express Patient Monitor are similar to the predicate device named PM-8000 Patient Monitor. Both PM-9000 Express and PM-8000 provide a means for interfacing with a patient, collecting parameter specific physiological data, and processing the data for alarm generation and display of numeric values and waveforms on a bedside or central monitoring system. The parameters' specification of the PM-9000 Express Patient Monitor, including ECG, RESP, HR, PR, RESP, NIBP, SpO_2, TEMP, IBP, is similar to the predicate PM-8000 Patient Monitor. The PM-9000 Express's specification of CO_2 and AG is similar to IntelliVue MP70.

The notable difference between the technical specifications of the PM-9000 Express and PM-8000 is shown as following:

The PM-9000 Express Patient Monitor provides optional CF memory card, which can be used as a mass storage for monitoring patient information.

For the monitoring parameters, while the specification of some parameters is different, but all these parameters of the pending device and the predicate device comply with ANSI/AAMI standards, IEC standards, EN standards and ISO standards.
The PM-9000 Express Patient Monitor provides two kinds of Temperature accessories applicable. YSI series and MR series. Both of them have same measurement range and accuracy, and both comply with EN12470-4.
For CO2, both the pending device and the predicate device with EN864, ISO9918; for AG, both the pending device and the predicate device comply with EN864, ISO11196, EN12598, EN7767.

These technological differences do not affect the safety or efficacy of the device. Any safety issues that may be raised by a software controlled medical device are the same issues already addressed by the predicate device and are addressed in the systems hazard analysis and in the system validation.

Testing:

Laboratory testing was conducted to validate and verify that the PM-9000 Express

Patient Monitor met all design specifications and was substantially equivalent to the predicate devices. This testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing was performed to demonstrate compliance with the ANSI/AAMI standards EC13-2002, "Cardiac monitors, heart rate meters, and alarms". Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation. Some safety testing has been performed by third party agencies to ensure the device complies with applicable industry and safety standards. The PM-9000 Express Patient Monitor has also been tested to assure compliance with the requirements of various published standards, including EN865, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-27, IEC60601-2-30, and ISO14971.
Testing of the non-invasive blood pressure portion of the system was conducted according to the requirements outlined in the ANSI/AAMI Standards SP10 "Electronic automated sphygmomanometers."

Although the device is neither life supporting nor life sustaining, diagnostic information derived from the use of the device and alarms generated by the device may be critical to the proper management of the patient. So, the areas of risk for this device are the same as other devices in this class, and the following:

- Electrical shock

  Excessive electrical chassis leakage current can disturb the normal electrophysiology of the heart.

- Misdiagnosis
  - Inadequate design of the signal processing and measurement circuitry or program can lead generation of inaccurate diagnostic data.. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - Inadequate design of the device's software, used to make various measurements, can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - Inadequate design of the systems ability to alert the users through audible and visual indicators, can lead to user mistrust and/or inadequate response to the patient's condition. If an inadequate response to the patient's condition should occur the patient may unnecessarily be placed at risk.

Conclusion:

The conclusions drawn from clinical and laboratory testing of the PM-9000 Express Patient Monitor demonstrates that the device is as safe, as effective, and

performs as well as or better than the legally marketed predicate device, the PM-8000 Patient Monitor numbered K#043348(by Mindray Co., Ltd) and the IntelliVue model MP70 numbered K# 030038(by Philips Co., Ltd.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2006

Shenzhen Mindray Bio-medical Electronics Co., Ltd.
c/o Ms. Susan Goldstein Falk
16 Electronics Avenue
Danvers, MA 01923

Re: K053234
Trade Name: PM-9000 Express Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: MWI
Dated: April 26, 2006
Received: April 27, 2006

Dear Ms. Falk:

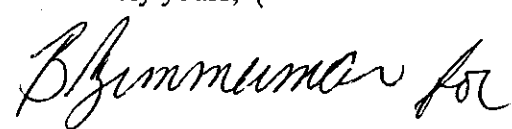
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053234

Exhibit #F

510(k) Number (if known): K053234

Device Name: PM-9000 Express Patient Monitor

Indications For Use:

The PM-9000 Express Patient Monitor is a vital signs monitor used on human patients. The target populations are adult, pediatric and neonatal patients. The PM-9000 Express Patient Monitor has many features and functions, yet is easy to use through an integrated keypad, knob and an intuitive menu system.

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Prescription Use __X___ (Per 21 CFR 801 Subpart D)

Over-The Counter Use _____ OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053234